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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,233	03/09/2004	Deger C. Tunc	OSTEONICS 3.0-305 DIV	2166

530 7590 09/07/2007  
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EXAMINER
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GODFREY, KEITH JOSEPH

ART UNIT	PAPER NUMBER
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1732

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/796,233	<b>Applicant(s)</b> TUNC, DEGER C.	
	<b>Examiner</b> Keith J. Godfrey	<b>Art Unit</b> 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/09/2004</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Roby et al. (US 6287499) in view of Harris (US 4209476).

**As to claim 1**, Roby et al. (US 6287499) teaches a method of making bioabsorbable filaments including: raising the extrusion temperature ensure a complete melt of the polymer (col. 2, lines 32-35); extruding the melt (extrudate) (col. 3, lines 34-41); quenching (cooling) the extruded melt filament in a bath (cooling bath) (col. 3, lines 37-39); passing the filament over a first godet (pullers) and second godet (pullers), the second godet (pullers) rotating at a higher speed than the first godet (pullers) (col. 3, lines 56-67 and Fig. 1, elements 21 and 24); and heating the filament as it passes between the first godet (pullers) and second godet (pullers) to a temperature between 40°C to about 140°C, the higher end of the range clearly suggesting temperatures above the glass transition (col. 4, lines 1-8 and Fig. 1, element 23).

Roby et al. (US 6287499) does not expressly teach specific controlling of the extrusion step.

Harris (US 4209476) teaches a method of fabricating extruded articles including controlling the volumetric rate of polymer material pumped to an extruding die by controlling the rate at which the extruder screw rotates (col. 2, lines 7-26 and col. 5, lines 60-68). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made it would have been obvious to modify the method of Roby et al. (US 6287499) to include the extruder controlling means, as taught by Harris (US 4209476), because controlling the rate at which the extruder screw rotates maintains a desired volumetric supply rate from the metering pump (Harris (US 4209476) col. 6, lines 8-10). Because both of the references are concerned with a similar technical field, namely that of manufacturing extruded articles, one would have a reasonable expectation of success from the combination.

**As to claim 2,** Roby et al. (US 6287499) teaches extruding polymer melt through and orifice of desired diameter (die) to provide a molten filament (col. 3, lines 34-41).

**As to claim 3,** Roby et al. (US 6287499) does not expressly teach controlling the extrusion rate using a feedback system.

Harris (US 4209476) teaches the use of a microprocessor (feedback system) for interpreting computed data and relating that against a predetermined value to control a constant volumetric rate using a metering pump (col. 5, lines 19-34; 60-68 and Fig. 1, elements 26 and 40). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Roby et al. (US

6287499) to include a microprocessor (feedback system), as taught by Harris (US 4209476), to ensure accurate control of the metering pump.

**As to claim 4**, Roby et al. (US 6287499) teaches a motor-driven metering pump supplied to an orifice (die) at a constant rate (col. 3, lines 34-37).

**As to claim 5**, Roby et al. (US 6287499) does not expressly teach the step of measuring the cross-section of the extrudate upon exiting the die.

Harris (US 4209476) teaches an exemplary method for controlling the average cross sectional area of an extrudate rod (filament) by provision of volumetric rate ( $V/t$ ) and length over time ( $N/t$ ) (col. 2, lines 27-41). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Roby et al. (US 6287499) to include measuring the cross sectional area of the extrudate, as taught by Harris (US 4209476), because maintaining size dimensions provides a more consistent product.

**As to claim 6**, Roby et al. (US 6287499) teaches the polymer melt before extrusion being heated to a temperature of about 50°C to about 240°C (col. 2, lines 22-24).

**As to claim 7**, Roby et al. (US 6287499) teaches a bath quenching temperature of 17°C (col. 5, line 35).

**As to claim 8**, Roby et al. (US 6287499) teaches the polymer polyglycolide (col. 2, lines 46-50).

**As to claims 9-10**, Roby et al. (US 6287499) teaches a heating oven between the first godet (pullers) and second godet (pullers) maintained at a temperature of about 40°C to about 140°C (col. 4, lines 1-7) clearly suggesting a temperature range between the glass transition temperature and the melting point.

**As to claim 11-12**, Roby et al. (US 6287499) teaches a type of stretching operation wherein the filament is drawn through a heating unit, which can be an oven chamber or a hot liquid (col. 3, lines 59-65).

**As to claim 13**, Roby et al. (US 6287499) teaches annealing the filament in a heating oven maintained at a temperature of about 40°C to about 140°C under tension between the first godet (pullers) and second godet (pullers) (col. 3, line 55—col. 4, line 10).

**As to claim 14**, Roby et al. (US 6287499) does not expressly teach that annealing is done for at least twenty minutes. However, it is submitted that an optimum annealing time period is desirable and can be optimized through routine experimentation (MPEP 2144.05 II A). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the annealing time period which can be done through routine experimentation.

**As to claim 15**, Roby et al. (US 6287499) teaches that the annealing operation would take place in a heating cabinet circulated with nitrogen and hot air (col. 4, lines 36-52).

**As to claim 16**, Roby et al. (US 6287499) teaches the heating units can be an oven chamber or a hot liquid trough (water bath) (col. 3, lines 64-66).

**As to claim 17**, Roby et al. (US 6287499) depicts a method of production wherein the production line is substantially parallel with the ground (horizontal plane) (Fig. 2).

**As to claim 18**, Roby et al. (US 6287499) depicts the initial extrudate melt bath quenching performed on a substantially vertical plane (Fig. 1, elements 16, 17, and 18)

**As to claim 19**, Roby et al. (US 6287499) teaches where upon exiting the die, the extrudate enters a quench bath where the filament solidifies (extrudate cools below glass transition temperature) (col. 3, lines 37-39).

**As to claim 20**, Roby et al. (US 6287499) teaches a temperature range that suggests temperatures below the melting point of the polymer—about 40°C (col. 4, lines 1-3).

**As to claim 21**, Roby et al. (US 6287499) teaches a method of making bioabsorbable filaments including: raising the extrusion temperature ensure a complete melt of the polymer (col. 2, lines 32-35); extruding the melt (extrudate) (col. 3, lines 34-41); quenching (cooling) the extruded melt filament in a bath (cooling bath) (col. 3, lines 37-39); passing the filament over a first godet (pullers) and second godet (pullers), the second godet (pullers) rotating at a higher speed than the first godet (pullers) (col. 3, lines 56-67 and Fig. 1, elements 21 and 24); heating the filament as it passes between the first godet (pullers) and second godet (pullers) to a temperature between 40°C to about 140°C, the higher end of the range clearly suggesting temperatures above the

glass transition (col. 4, lines 1-8 and Fig. 1, element 23); and an on-line relaxation, or shrinkage, of the filament (releasing tension) for a recovery (col. 4, lines 13-19).

Roby et al. (US 6287499) does not expressly teach specific controlling of the extrusion step.

Harris (US 4209476) teaches a method of fabricating extruded articles including controlling the volumetric rate of polymer material pumped to an extruding die by controlling the rate at which the extruder screw rotates (col. 2, lines 7-26 and col. 5, lines 60-68). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made it would have been obvious to modify the method of Roby et al. (US 6287499) to include the extruder controlling means, as taught by Harris (US 4209476), because controlling the rate at which the extruder screw rotates maintains a desired volumetric supply rate from the metering pump (Harris (US 4209476) col. 6, lines 8-10).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith J. Godfrey whose telephone number is 571-272-6391. The examiner can normally be reached on 8:00-5:00 Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on 571-272-1176. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kjg

  
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SUPERVISORY PATENT EXAMINER